This report is required by law (7 USC 2143). Failure to report acc[illegible]g to the regulations can result in an order to cease and desist and to be subject to penaliti[illegible]rovided for in Section 21!

See attach[illegible]orm for additiona[illegible]mation.

Interagency Report Control No. C-a

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. CERTIFICATE NUMBER: 16-R-0029
CUSTOMER NUMBER: 55

FORM APPROVED
OMB NO. 0579-0036

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

Telephone: (203) -798-9988

OCT 27 2003

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Alached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals a the reasons such drugs were not used must be attached this report).	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	64	99	25	24	148
5. Cats					
6. Guinea Pigs			128	60	188
7. Hamsters					
8. Rabbits				6	6
9. Non-human Primates	196		6	105	111
10. Sheep					
11. Pigs	43		19		19
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
		10/21/03

APHIS FORM 7023 (Replaces VS FORM 18-23 (OCT 88), which is obsolete.)
(AUG 91)

The 24 dogs assigned to column E of this report were included in toxicology or safety assessment procedures in which, to meet Food and Drug Administration requirements under Good Laboratory Practice regulations (21 CFR 58.120, 43 CFR 60013) a limited number of animals must be exposed to test compound dose levels toxic to the animal. Clinical signs produced by some test compounds at toxic dose levels may be distressful or painful to the animal, if only transiently. To intercede prematurely would invalidate the procedure, requiring its repetition and the consequent use of more animals.

The 60 guinea pigs assigned to column E of this report were included in toxicology or safety assessment procedures in which, to meet Food and Drug Administration requirements under Good Laboratory Practice regulations (21 CFR 58.120, 43 CFR 60013) positive control animals must be sensitized, then challenged by intradermal injection resulting in a transient inflammatory response, which may be distressful or painful to the animals albeit for a strictly limited period. To intercede prematurely would invalidate the procedure, requiring its repetition and the consequent use of more animals.

The 6 rabbits assigned to column E of this report were used for hyperimmunization procedures (polyclonal antibody production) in which adjuvant associated with the antigen of interest produced localized discomfort typical of a subacute inflammatory reaction. The lesions were treated topically to minimize discomfort, and in all cases the minimum quantity of least irritating adjuvant was employed that would not have necessitated the use of additional animals. The protocol permits 10-20 intradermal injection sites which may be pruritic or transiently painful when subjected to normal postural adjustments. The use of systemic analgesics during the several week duration of the process is regarded as inappropriate, since these agents interfere with the antibody production process (e.g., corticosteroids), or have systemic side effects in chronic dosage (appetite suppression, constipation). Although the injection sites are monitored daily for signs of excessive inflammation and treated locally with emollients, local anesthetics and antibiotics as indicated, a conservative classification acknowledges the potential for distress associated with what is an iatrogenic dermatitis.

Primates assigned to column E of this report were used in various toxicology/safety assessment procedures, pharmacologic studies of the inflammatory response or evaluation of the immunomodulatory effects of test compounds.

12 cynomolgus macaques were injected parenterally with compounds intended to produce early physiologic changes associated with systemic shock. Although doses are titrated to produce the minimum physiologic change compatible with the appropriate evaluation of the test anti-inflammatory compound, normal physiologic variation among animals, the side effects of up to four hour sedation throughout the test period and repeated use of the same animals to test a succession of compounds produces transient anorexia and limited signs of depression during the 24-hour post-test period. We feel this could be distressful to the animal and have conservatively assessed the procedure accordingly.

23 squirrel monkeys are used as a model of [redacted] in which they are sensitized by antigen in an adjuvant vehicle appropriate to the route, dosed with test compound by a variety of routes and then skin tested with the original antigen. Although antigen dose is minimized, systemic reactions include inappetence and depression; local reactions at injection sites are those associated with minimal acute inflammation. Discomfort is attenuated through the use of analgesic drugs but, because an inflammatory condition is induced and clinical signs may appear, it is anticipated that the monkeys may potentially experience the discomfort which human beings feel during the analogous condition.

70 rhesus macaques were included in toxicology or safety assessment procedures in which, to meet Food and Drug Administration requirements under Good Laboratory Practice regulations (21 CFR 58.120, 43 CFR 60013) a limited number of animals must be exposed to test compound at dose levels toxic to the animal. Clinical signs produced by some test compounds at toxic levels may be distressful or painful to the animal, if only transiently. To intercede prematurely would invalidate the procedure under the cited regulations, requiring repetition of the study and the consequent use of more animals.